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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
097508,195	03/05/00	HARDERN	3764-2

NIXON & VANDERHYE  
8TH FLOOR  
1100 NORTH GLEBE ROAD  
ARLINGTON VA 22201-4714

HM22/0613

EXAMINER

FORD, J

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 06/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/508/95

Applicant(s)

Hardern et al

Examiner

J. M. Ford

Group Art Unit

1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on March 2 2000
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1-18 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-6 and 17 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☒ Claim(s) 7-16 and 18 are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☒ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☒ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

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The claims in the application are claims 1--18.

The compounds of formula I are taken to be applicants elected compound invention in this application.

This is a 371 application, 37 CFR 1.475 makes it very clear that applicants get one compound invention examined in the application.

In the case of multiple products such as are found in claim 18, applicants are restricted to one. That is taken to be claim 1 by clear preponderance of species.

The species in claim 18 that are not 1, 2, 3-triazole [4, 5-d] - pyrimidines are taken to be the multiple product restricted out of this application.

Claims 1, and 5 are rejected under 35 U.S.C. 112, 2nd paragraph. What is "or solvate thereof"? What is the solvent? What does it react with? What is the structure of the product?

What is the purpose of the proviso statement at the end of claim 1?

This proviso is taken to represent prior art compounds.

When applicants remove certain compounds, certain other next adjacent or analogous compounds are left in the genus and still claimed. The compounds that are left would be structurally obvious from the ones removed.

Claim 1 is rejected under 35 U.S.C. 103, note the proviso statement at the of the end of the claim. Closely related structurally obvious compounds to those removed by exception would be obvious. The adjacent species to those specifically removed would be obvious therefrom.

E.g., Dillon, 919 F.2d at 696, 16 U.S.P.Q. 2d at 1904.

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See also Deuel, 51F. 3d at 1558, 34 U.S.P.Q. 2d at 1214

(‘Structural relationships may provide the requisite motivation or suggestion to modify known compounds. To obtain new compounds. For example, a prior art Compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties.’)

Other structural similarities have been found to support a prima facie case of obviousness. E.g., In re May, 574 f.2d 1082, 1093-95, 197 U.S.P.Q. 601, 610-11 (CCPA 1978)(stereo-isomers); In re Wilder, 563 F2d 457, 460, 409 (CCPA 1970)(Acid and ethyl ester); In re Druey, (omission of methyl group from pyrazole ring).

What is the purpose of the proviso at the end of claim 1? It is assumed that those are known compounds.

A piece of prior art is not necessary. We reject on compounds not citations. No reason is seen not to assume that applicants are saying those compounds removed by proviso are in the prior art. In re Nomiya et al., 184 USPQ 607, indicates that is a reasonable assumption, and that a rejection based on the compounds as prior art is acceptable, even if we do not know what the citation of that prior art compound(s) is/are.

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Therefore, claim 1 is rejected under 35 U.S.C. 103 as being structurally obvious from the compounds removed by exception. Note in re Nomiya et al., 184 U.S.P.Q. 607. We reject on compounds, not citations. The compounds removed by exception are presumed known.

Claims 7--13 violate 35 U.S.C. 101 and 35 U.S.C. 112, since drafted in terms of use. See *Clinical Products vs. Brenner*, 255 F. Supp. 151; 149 USPQ 475 (D.C. District Columbia 1966).

Claims 14--16 are too broadly claimed, as "prevention" is very difficult to show.

MPEP 806.05(h) provides for the ability to restrict out claims 7--16, as they are not directed solely to one method of use in currently variable form. 37 CFR 1.475 provides that applicants may have one believable use of their compounds examined therewith.

Applicants should pick one use from claims 7--16, and word the claims in U.S. claim form. A composition and a method claim.

Applicants should pick one believable utility they can demonstrate.

The recent utility guidelines set by PTO require applicants to meet the requirements as stated in *Brenner v. Manson* in 148 USPQ 689, which requires that utility be developed to a point where "specific benefits exist in currently available form". Similar is the "immediate benefit to the public" standard that *Nelson v. Bowler*, 206 USPQ 880 refers to. The standard set forth in the concurring opinion of *In re Hartop*, 135 USPQ 419 is "whether the invention has been brought to such perfection as to be capable of practical employment". This language is echoed in *Bindra vs. Kelly*, 206 USPQ 570.

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MPEP 806.05(h) provides for one method of use to be examined with the elected compounds. A broad disclosure of utility, as in the cited claims, cannot be deemed in compliance with 35 U.S.C. 101, and 35 U.S.C. 112, first paragraph.

The PTO has amended the guidelines to clarify "specific utility.". The court focused on the fact that the applicant failed to identify a "specific utility" in *Brenner v. Manson*.

This requirement of one specific utility is consistent with 37 CFR 1.475 Unity of Invention Practice in International, Applications and National Phase Applications under 35 U.S.C. 371, and PCT Rule 13.2 for PCT application. Therefore, applicants should limit the method claims to a "specific utility".

Claim 17 is rejected under 35 U.S.C. 112, 2nd paragraph. It is not understood in the last second lines of claim 17 what the solvate is or how it is prepared. What is the solvent. What portion of formula I does it react with? What is the structure of the solvate final product with formula I?

Claim 18 contains multiple products. Claim 1 is considered the product being examined here.

The following compounds need to be removed from claim 18, as outside any reasonable extension of claim 1:

(1S-cis)-2-[[4-[[6-Chloro-5-nitro-2-[(3,3,3-trifluoropropyl)thio]-4-pyrimidinyl]amino]-2-cyclopenten-1-yl]-acetic acid, ethyl ester;

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found near the end of page 49.[3aS-(3a ,4 ,6 ,6a )-tetrahydro-6-hydroxy-2,2-dimethyl-4H-cyclopenta-1,3-dioxol-4-yl]-carbonamic acid, phenylmethyl ester;

[3aS-(3a ,4 ,6 , 6a ,)-[2,2-Dimethyl-6-(2-hydroxyethoxy)-tetrahydro-4H-cyclopenta-1,3-dioxol-4-yl]-carbamic acid, phenylethyl ester;

[3aR-(3a ,4 ,6 ,6a )]-2-[[6-Amino-2,2-dimethyl-tetrahydro-4H-cyclopenta-1,3-dioxol-4-yl]oxy]-ethanol;

2-(Butylthio)-4,6-dichloropyrimidine-5-amine;

[3aR-(3a ,4 ,6 ,6a )]-2-[[6-[[5-Amino-2-(butylthio)-6-chloro-pyrimidin-4-yl]amino]-tetrahydro-2,2-dimethyl-4H-cyclopenta-1,3-dioxol-4-yl]oxy]ethanol;

found near the end of page 50.

These above identified claims need to be removed from claim 18. Applicants may rely on the protection of 35 U.S.C. 121 in regard to a divisional application, as these species are being restricted out here. See 37 CFR 1.475 and 1.499.

Claims 2--4 and 6 are rejected as being dependent on a rejected claim.

Claims 7--16 are subject to a restriction requirement to one specific believable demonstratable utility.

Claim 18 need be limited to the invention of claim 1. Multiple invention are not permitted in 371 applications.

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

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The "Abstract" is a little thin. Please include a formula. The Abstract has become a main search display, because of the change in the layout of a printed Patent.

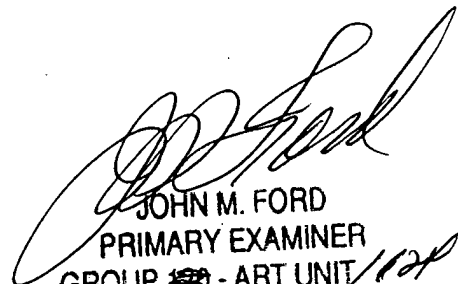
Please insert on page 1 of the specification after the title: This is a 371 National application of PCT/SE 99/02256.

Any inquiry concerning this communication should be directed to John M. Ford at telephone number (703) 308-4721.

J. Ford:jmr

December 11, 2000

December 18, 2000

  
JOHN M. FORD  
PRIMARY EXAMINER  
GROUP ~~18~~ - ART UNIT ~~1624~~